EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 28 2013

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Re: Docket No. FDA 2007-P-0122 and 2006-P-0338 (Previously 2006-P-0394 and 2007-P-0235)

Dear Ms. Meier, Ms. Leahy, Ms. Bock, and Ms. Share:

This letter is in response to your citizen petition, dated September 21, 2010, which "supplant[ed]" your previous petitions, requesting the Food and Drug Administration (FDA) to revise the current labeling requirements for shell eggs sold in the United States. Specifically, your 2010 petition requests that FDA require, via regulation, shell eggs to bear one of three labels: "Free-Range Eggs," "Cage-Free Eggs," or "Eggs from Caged Hens." Further, you provide descriptions of production conditions that would be associated with each term. Finally, you provide definitions of the terms "egg," "cage," "barn," and "label" for FDA to adopt via regulation.

You contend that current labeling of shell eggs "fails to reveal to consumers certain material facts that substantially influence their purchasing decisions" (Pet. at 2).

You further contend that information regarding how eggs are produced is a material fact because: (1) consumers "would be willing to pay more for eggs they believe to have been produced in a humane manner"; (2) "eggs from caged hens are nutritionally inferior to [eggs] from pastured free-range birds"; and (3) "eggs from [caged hens] have an increased risk of being contaminated with [Salmonella Enteritidis]" (Pet. at 4, 28, 57).

DECISION SUMMARY

After careful review of your citizen petition and for the reasons described below, FDA is denying your citizen petition in accordance with 21 Code of Federal Regulations (CFR) 10.30(e)(3) because you do not provide a sufficient basis for the agency to revise the current labeling requirements for shell eggs. Specifically, you have not provided evidence sufficient to show that eggs from caged hens are "nutritionally inferior" to eggs from free-range and cage-free hens. Therefore, nutritional properties cannot provide a basis to consider the method of production for eggs to be a material fact. Moreover, nutritional information regarding particular eggs is conveyed to consumers directly by placing the particular nutrient information on the label, not by identifying the method of production, which does not provide consumers with information as to nutritive content. Second, you have not provided sufficient evidence to show that eggs from caged hens have a greater risk of Salmonella contamination than eggs from the other two production methods you define; consequently, the risk of Salmonella cannot provide a basis to consider the method of production for eggs to be a material fact. Finally, even assuming the method of egg production may be of interest to some consumers, consumer interest alone is not a material fact. Therefore, FDA is not compelled under the Federal Food, Drug, and Cosmetic Act ("the Act") or its implementing regulations to require labeling of egg production methods nor could the agency require such labeling under the law. Finally, even if the agency could require such labeling, it would choose to use its limited resources on rulemakings of higher priority, such as those that are of greatest public health significance or are statutorily-mandated.

I. RELEVANT LEGAL AND REGULATORY BACKGROUND

A. MATERIALITY

1. Scope

Under section 403(a)(1) of the Act, (21 U.S.C. 343(a)(1)), a food is misbranded if its labeling is false or misleading in any particular. Both the presence and absence of information on labeling can be misleading. Regarding absence of information, labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (21 U.S.C. 321(n)). The agency has interpreted the scope of "materiality" to mean information about the attributes of the food itself. FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: (1) pose special health or environmental risks (e.g., warning statements on protein products used in very low calorie diets); (2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are

made); or (3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles, when in fact it does not (e.g., reduced fat margarine that is not suitable for frying).

2. *Consumer Interest*

Your petition is not the first time that someone has asserted that consumer interest is the test for materiality. In Stauber v. Shalala, 895 F. Supp. 1178 (W.D. Wis. 1995), plaintiffs challenged FDA's approval of Posilac (rbST), a genetically engineered animal drug approved for use in dairy cows to enhance milk production. As part of that challenge, plaintiffs alleged that FDA was required to mandate labeling of products from cows treated with the drug. Id. at 1193. The court noted that FDA received thousands of letters from consumers asking FDA to deny approval of rbST or to require labeling of rbST products. Id. at 1183.

Plaintiffs argued that food products from rbST-treated cows must be labeled as such to comply with 21 U.S.C. 343(a)(1) and 321(n). Id. at 1193. Specifically, plaintiffs argued that widespread consumer desire for mandatory labeling was a "material fact" requiring labeling. Id. However, in its response to this assertion regarding consumer desire, the court affirmed FDA's long-standing interpretation regarding materiality and stated:

> Regarding widespread consumer demand, plaintiffs are incorrect in their assertion that by itself consumer opinion could suffice to require labeling. . . . In the absence of evidence of a material difference between rbST-derived milk and ordinary milk, the use of consumer demand as the rationale for labeling would violate the [Act].

Id. at 1193.

Five years later, a court upheld another FDA decision not to mandate, on the basis of consumer interest, labeling for a production method. In Alliance for Bio-Integrity v. Shalala (ABI), plaintiffs challenged FDA's policy not to consider rDNA modification to be a "material fact" and therefore not to require labeling of rDNA-produced foods. 116 F. Supp. 2d 166, 170 (D.D.C. 2000). Plaintiffs claimed that FDA should have considered the widespread consumer interest in having genetically engineered foods labeled, as well as the special concerns of religious groups and persons with allergies. Id. at 178. The court rejected plaintiffs' argument that consumer demand was a material fact under 21 U.S.C. 321(n):

> More specifically irksome to the plaintiffs, the FDA does not read § 321(n) to authorize labeling requirements solely because of consumer demand. The FDA's exclusion of consumer interest from the factors which determine whether a change is "material" constitutes a reasonable interpretation of the statute. Moreover, it is doubtful whether the FDA would even have the power under the FDCA to require labeling in a situation where the sole justification for such a requirement is consumer demand.
>
> Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they fail to recognize

> that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact.

Id. at 179. The court also rejected plaintiffs' argument that the process of a genetic modification is a material fact because the Act does not require disclosure of how a food is produced without regard to its effect on the product:

> Disclosure of the conditions or methods of manufacture has long been deemed unnecessary under the law. The Supreme Court reasoned, "[w]hen considered independently of the product, the method of manufacture is not material. The act requires no disclosure concerning it." U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 445 (1924).

Id. at 179 n.10.

B. EXISTING REGULATIONS GERMANE TO THIS PETITION

1. Egg Safety Regulations

On July 9, 2009, FDA issued a final regulation to address egg safety titled "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation" (74 FR 33030). Since July 9, 2012, egg producers with 3,000 or more laying hens have been required to comply with the rule's comprehensive requirements (74 FR at 33034). The shell egg regulation applies to all types of egg production (e.g., caged, cage-free, and free range)[1] and is expected to prevent each year approximately 79,000 cases of foodborne illness and 30 deaths from consumption of eggs contaminated with Salmonella Enteritidis (SE).

The shell egg rule requires egg producers to implement measures to prevent SE from contaminating eggs on the farm and during storage and transportation (21 CFR Part 118). It requires egg producers to have and implement SE Prevention Plans with measures to address pullets, biosecurity, pest control, refrigeration, and cleaning and disinfection (21 CFR 118.4) It also contains comprehensive testing requirements, including mandatory environmental testing of every poultry house for SE (21 CFR 118.5). Further, if an egg tests positive for SE, all eggs from that house must be diverted from the table egg market to a treatment that will destroy any SE that may be present until four subsequent tests of eggs from the house are negative for SE (21 CFR 118.6). Producers must register with FDA and maintain records to document their compliance with the rule (21 CFR 118.10, 11).

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[1] *See, e.g.*, Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access) (providing guidance to egg producers on certain provisions in the egg rule concerning the management of production systems that provide laying hens with access to the outdoors), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm360028.

Additional requirements apply to shell eggs at the retail level. Shell eggs must be promptly placed under refrigeration upon receipt at a retail establishment and must be stored and displayed under refrigeration at an ambient temperature not greater than 7.2 °C (45 °F) (21 CFR 101.50). In addition, shell egg cartons are required to be labeled with the following safe handling instructions to prevent illness from the growth of SE (21 CFR 101.17(h)):

> SAFE HANDLING INSTRUCTIONS: To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly.

2. Nutrition Labeling Regulations

The Act and its implementing regulations require packaged shell eggs to be labeled with the same information that is required on other FDA-regulated packaged foods. The Nutrition Facts label must include certain nutrition information, such as the amount of saturated fat, cholesterol, and vitamin A (21 CFR 101.9(c)(2)(i), (c)(3), and (c)(8)(ii)). Other nutrition information is not required but may be provided on the Nutrition Facts label, including the amount of vitamin B12, vitamin E, and folic acid (21 CFR 101.9(c)(8)(ii)(B)). The amount of omega-3 fatty acids may be provided outside the Nutrition Facts label (21 CFR 101.13(i)(3)).[2] The egg packager is responsible for ensuring that the nutrition information provided on the label accurately reflects the nutritional profile of the food. If the label does not include the mandated information, or any of the information provided is false or misleading, the product is subject to enforcement action (*See,* e.g., 21 U.S.C. 343(a), 331(a)-(c), (k), and 334(a), (h)).

II. ANALYSIS

A. PRODUCTION METHOD AND NUTRITIONAL PROPERTIES OF EGGS

1. Evaluation of Information Submitted

In your petition you assert that "[r]ecent studies demonstrate the nutritional inferiority of cage-produced eggs to pastured free-range eggs" (Pet. at 25). We have carefully reviewed these studies, and we find them insufficient to support a categorical determination regarding the relative nutritional properties of eggs based solely on the method of production.

None of the references cited (Gorski, 2000[3]; Long and Alterman, 2007[4]; Tolan et al., 1974[5]; Karsten et al., 2010[6]; Lopez-Bote et al., 1998.[7]; Simopoulos, 2001[8]) was designed in a way that

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[2] *See* Guidance for Industry: A Food Labeling Guide (8. Claims) Question and Answers N21 and N22.
[3] Gorski, B. 2000. Nutritional Analysis of Pastured Poultry Products. *APPPA GRIT (American Pastured Poultry Producers Association*). Winter 2000, Issue 11. Page 1-3 (Pet. Ex. 64).
[4] Long, C. and T. Alterman, 2007. Meet real free-range eggs. *Mother Earth News* http://www.motherearthnews.com/real-food/tests-reveal-healthier-eggs.aspx#axzz2W2JoF4py (Pet. Ex. 56).
[5] Tolan, A, J. Robertson and C.R. Orton, 1974. The chemical composition of eggs produced under battery, deep litter and free range conditions. *Br J Nutr*. 31:185-200 (Pet. Ex. 61).
[6] Karsten, H.D., P.H. Patterson, R. Stout, and G. Crews, 2010. Vitamins A, E and fatty acid composition of the eggs of caged hens and pastured hens. *Renewable Agriculture and Food Systems*. 25(1):45-54 (Pet. Ex. 63).

would demonstrate the nutritional inferiority of cage-produced eggs to pastured free-range eggs. A well-designed study seeking to determine whether there is a nutritional difference based on production method alone would need to control for all other variables. None of the studies submitted with the petition did this comparison (i.e., compared caged hens with free-range hens fed the same food).

The Gorski (2000) report is not a true comparative study with appropriate controls but rather a comparison to a USDA egg nutrient database. Four free-range operations submitted egg samples to a commercial laboratory for nutritional analysis and based their reported findings on a comparison to the USDA database. The report found that the free-range eggs had higher levels of vitamin A and a "better" ratio of omega-6 to omega-3 fatty acids. The report provides no specific details about the age, breed, diet, or environmental conditions of the hens from which the USDA compiled the database. It is quite likely that all those factors differed significantly from the conditions for each of the four free-range farms in the study. Diet, in addition to several other factors, including age, breed, strain, and environmental conditions, plays a key role in determining the nutrient content of eggs (Stadelman and Cotterill, 1995[9]; Bell and Weaver, 2002[10]). Because there were no specific details on how the database was established and because there was no statistical evaluation of the data, the report cannot support broad conclusions regarding any apparent differences in the eggs. Further confounding the study, the free-range hens producing eggs were supplemented with several sources of omega-3: fish meal, seaweed, and flax seed; it is therefore not surprising that they would produce eggs with elevated levels of omega-3 fatty acids. A similar result would be expected for caged hens if their diet was similarly supplemented.

Similar to the Gorski (2000) report, the Long and Alterman (2007) article compared eggs to a USDA egg nutrient database. The article compared six eggs from either free-range or "moveable pens" production systems from fourteen farms to the USDA database. The study reported finding lower cholesterol and saturated fat along with elevated levels of vitamin A and E, omega-3 fatty acids, and carotene in the free-range and moveable pens-produced eggs. Like the Gorksi report, the Long and Alterman study also lacks an appropriate control group, which makes it impossible to draw conclusive results. Further, given the lack of specific details on the data included in the USDA database (e.g., age, breed, diet), any comparisons are of very limited value.

The work of Simopoulos (2001) also involved comparison to the USDA database and thus is subject to the same limitations as Gorksi (2000) and Long and Alterman (2007) (i.e., no appropriate control, lack of information regarding conditions of egg production for eggs in the

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[7] Lopez-Bote, C.J., R.S. Arias, A.I. Rey, A. Castaño, B. Isabel, and J. Thos, 1998. Effect of free-range feeding on n-3 fatty acid and α-tocopherol content and oxidative stability of eggs. *Animal Feed Science Technology*. 72:33-40 (Pet. Ex.65).

[8] Simopoulos, A.P., 2001. The Mediterranean Diets: What is so special about the diet of Greece? The scientific evidence. *Journal of Nutrition*(131) 3065S-3073S (Pet. Ex. 62).

[9] Stadelman, W.J. and O.J. Cotterill, 1995. *Egg Science and Technology, 4th Ed.* Food Products Press. The Haworth Press, Inc, New York-London. Pp. 177-194.

[10] Bell, D.D., and W.D. Weaver Jr., 2002. *Commercial Chicken Meat and Egg Production, 5th Ed.* Springer. Pp. 1116 and 1124.

database). In addition, the free-range pastured hens whose eggs were compared to the USDA database ate a diet of "grass, purslane [a wild plant], insects, worms, and dried figs, all good sources of [omega-3] fatty acids." Given the role of diet, it is therefore not surprising that they would produce eggs with elevated levels of omega-3 fatty acids.

The Tolan et al. (1974) study compared the nutrient content of eggs produced in battery (cages), deep litter (on the floor in pens), and free-range (free access to grass) production systems. The production systems utilized varying management systems, diets, and hens. The study found that free-range eggs had more vitamin B12 and folic acid compared to cage-produced eggs, but the study has some significant limitations, which the authors acknowledge. One key limitation of the study was the origin of egg samples submitted for analysis: eggs were collected from research farms in various locations, and hens producing them were of different breeds and fed different diets. These two factors affect egg composition; therefore, differences in vitamin B12 and folic acid could be attributed to these factors (i.e., breed and diet) and not necessarily to the type of production system from which they originated. Given that hens in this study were of different breeds and ages and consumed differing diets, the authors clearly indicate that differences in nutrient composition were more likely a result of which research farm raised the hen than the production system used by that farm (caged vs. cage-free).

The Karsten et al. (2010) study examined how moving free range hens between various pastures with different vegetation influenced omega-3 fatty acid, vitamin A, and vitamin E concentrations, and compared eggs from free-range systems to caged hens on a commercial diet. Although levels of vitamin E and total omega-3 fatty acids in eggs from free-range hens were elevated in this study, these differences could be attributed to the diet, not the production system (caged vs. free-range). Hens fed on pasture within the experiment were rotated through three different types of pastures, including grass, alfalfa and clover, while the caged hens remained on the same diet the entire study. Given the influence that diet has on egg composition, the pastured free-range hens' variation in diet could be responsible for the observed nutrient differences.

Finally, the Lopez-Bote et al. (1998) study compared the fatty acid and vitamin E content, as well as susceptibility to oxidation, of egg yolks from free-range and caged hens on a commercial diet. This study closely mirrors the Karsten et al. (2010) study in that levels of vitamin E and omega-3 fatty acids were found to be significantly different in cage-free and cage-produced eggs. The study design had two variables: housing type (caged vs. free range) and diet (commercial diet for caged hens vs. pasture vegetation with commercial diet supplementation for free-range hens). This design did not allow for determination of which of these two variables lead to the differences in vitamin E and omega-3 fatty acid concentration. Therefore, it is incorrect to implicate cages (i.e., housing type) as the defining factor resulting in the differences that were observed because diet could be responsible for the differences.

2. *The Information Submitted Does Not Support the Proposed Labeling Requirements*

The information you provide is insufficient to establish a nutritional difference in egg composition between caged hens and free-range hens that would warrant the required labeling you propose in your Petition for three reasons. First, as explained in detail above, the studies you provide contain other variables such as feed, season, age, and breed, which could account for any

nutritional differences between eggs from pastured free-range hens and eggs from caged hens. These studies have limitations–their failure to control for other variables–which make it impossible to determine whether any of the observed differences can be attributed to the production environment.

Second, the studies you provide cannot support your proposed definitions because the studies either fail to provide enough information to determine whether the eggs in the studies were produced in the same conditions described in your proposed definitions, or the studies consider egg production conditions that are notably different than the ones you propose.[11] For example, your definition of "free-range eggs" does not require that hens be rotated among three pasture treatments as they were in Karsten (2010), does not require that hens "wander on farms, eat grass, purslane, insects, worms, and dried figs" as they did in Simopoulos (2001), and does not include hens that are housed in moveable pens, as some hens were in Long and Alterman (2007). There is not enough information to determine whether the production conditions in Gorski (2000) and Tolan (1974) for free-range pastured hens are the same as the conditions in your proposed definition of "free-range eggs." Also, your definition of "cage-free eggs" does not require access to pasture, unlike the egg production conditions in Gorski (2000), Karsten (2010), Lopez-Bote (1998), Tolan (1974), Simopoulos (2001), and some of the conditions in Long & Alterman (2007). Because the studies reflect conditions that are not the same as the ones you propose for "cage free" and "free-range," they cannot support your proposal.

Third, the nutritional properties you reference are themselves already either required or allowed to be provided on the label under existing FDA regulations. Therefore, to the extent that a material fact is implicated, the labeling for these nutritional differences is already regulated by the Act and its implementing regulations. Further, it is these nutrient characteristics—and not the method of production—that would convey the nutritional information to consumers. A label of "free-range eggs," "cage-free eggs," or "eggs from caged hens" would not inform consumers about the specific levels of nutrients in those eggs; that information is only conveyed by providing the specific levels of nutrients in each egg. This information is already required[12] (e.g., saturated fat, cholesterol, and vitamin A) or permitted[13] (e.g., vitamin B12, vitamin E, folic acid, and omega-3 fatty acids) on the label. If the required information is not provided or any of the information is false or misleading, the product is (already) subject to enforcement action. *See, e.g.*, 21 U.S.C. 343(a), 331-334; *See also infra* section II. F.

B. PRODUCTION METHOD AND SALMONELLA PREVALENCE IN EGGS

1. Evaluation of Information Submitted

You assert that there is a connection between the production of eggs from caged hens and the risk of Salmonella contamination (Pet. at 57). We have carefully reviewed the studies you provide, and we find them insufficient to establish that, based on production method alone (i.e., free-range, cage-free, and caged), a conclusion about the relative risk of Salmonella in particular

[11] We note that you acknowledge that "not all eggs that qualify as 'free range' are the pastured eggs that were the subject of these studies…." (Pet. at 28).
[12] 21 CFR 101.9(c)(2)(i), (c)(3), and (c)(8)(ii).
[13] 21 CFR 101.9(c)(8)(ii)(B); 21 CFR 101.13(i)(3).

eggs can be made. In fact, most of the studies you reference (Van Hoorebeke et al., 2010[14]; Dewulf, 2010[15]; Holt et al., 2011[16]) conclude that there was no difference between the two production methods, that a move to cage-free system should not increase Salmonella prevalence, or that insufficient data exist to deem one system superior with respect to Salmonella risk. Also, some of the data within the references (Holt et al., 2011; Huneau-Salaün et al., 2009[17]; Dewulf, 2010; Van Hoorebeke et al., 2010) indicate that in some situations cage-free systems can lead to a higher incidence of Salmonella-positive environments (presence of Salmonella where the hens are). Further, in two of the studies (EFSA, 2007[18]; Huneau-Salaün et al., 2009) caged and cage-free environments are sampled using different schemes that have different sensitivities for detecting Salmonella in the environment.

In addition, you assert that caged production systems generally are more susceptible to Salmonella contamination because of the presence of manure pits (Pet. at 62). Although caged systems with manure pits (often referred to as high-rise houses) are common, not all caged operations have pits. Moreover, some caged operations, such as manure belted operations, are specifically designed to eliminate manure from the production environment on a near continuous basis. Considered together, the references you provide are insufficient to support your view that "caged hens are producing eggs at significantly higher risk of disease" (Pet. at 64). Each reference is discussed below.

The EFSA (2007) study was a European Union-wide baseline study aimed at determining the prevalence of Salmonella in commercial farms in Europe with at least 1,000 hens. The study has a number of limitations. The experimental design does not allow one to determine whether the true risk factor was the use of cages or the size of flocks. As the authors state, "it was not possible to determine which of these two factors was a true risk factor for positivity." Large flock size is implicated as a risk factor in other studies you reference (Dewulf, 2010; Huneau-Salaün et al., 2009; Holt et al., 2011). In addition, the production systems were sampled differently. Caged flocks were sampled by collecting pooled fecal samples (hand collected) while cage-free flocks were sampled with boot swabs (special shoe covers). The sampling schemes used differ in their sensitivity. Finally, there were contradictory data within the study in that the prevalence of Salmonella in barn and organic flocks was higher than caged flocks in some circumstances.

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[14] Van Hoorebeke et al. 2010. Determination of the within and between flock prevalence and identification of risk factors for Salmonella infections in laying hen flocks housed in conventional and alternative systems. *Prev Vet Med*(94): 94-100 (Pet. Ex. 93).

[15] Dewulf, J, 2010. Salmonella thrives in cage housing. *World Poultry Net* http://www.worldpoultry.net/Breeders/General/2010/5/Salmonella-thrives-in-cage-housing-WP007481W/. Accessed May 16, 2013 (Pet. Ex. 90).

[16] Holt, et al., 2010. The impact of different housing systems on egg safety and quality. *Poultry Science*. In press (Pet. Ex. 96).

[17] Huneau-Salaün, et al., 2009. Risk factors for Salmonella enterica subsp. Enterica contamination in 519 French laying hen flocks at the end of the laying period. *Prev Vet Med* (89): 51-58 (Pet. Ex. 94).

[18] EFSA, 2007. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of Salmonella in holdings of laying hen flocks of Gallus gallus. *EFSA Journal* (97):1-84 (Pet. Ex. 97).

The Van Hoorebeke et al. (2010) study was designed to determine the between and within flock prevalence of hens shedding Salmonella, to identify Salmonella risk factors, and to evaluate the effect of housing type on Salmonella prevalence. This study has a number of limitations. The caged systems sampled were older than the cage-free systems included in the study. Salmonella can survive in the environment for extended periods of time (Davies and Wray, 1996[19]; Davies and Breslin, 2003[20]); as a consequence, as building infrastructure ages the population of Salmonella at that location builds creating an "environment load" or resident population of Salmonella that is difficult to eliminate completely. Thus building age should always be considered a factor when considering the effect of a certain building type on the microbiological population of eggs. The authors specifically state: "The effect of the age of the infrastructure may be explained by the fact that the older the infrastructure, the more difficult it gets to achieve sufficient standards of cleaning due to the wear of the material, both of the production system and of the building itself, especially when it is taken into account that the level of environmental contamination increases significantly during a production cycle." (Wales et al., 2007[21]). The authors concede that "[i]n this study the age of conventional battery cages was significantly higher than that of the floor-raised, free-range and organic systems." Thus, the differing ages of the house types compared could have affected findings related to the prevalence of Salmonella. Further, the authors acknowledge that transmission of Salmonella from ingestion of contaminated feces (oral-fecal route) is higher in cage-free systems. The paper notes that in Switzerland bacterial infections in chicks and laying hens increased after cages were banned.

The Dewulf (2010) report was not a study but rather a discussion of multiple studies. The report focused on identifying and explaining multiple factors that could affect the prevalence of Salmonella on egg laying farms, including housing system, flock size, stress factors, building age, rodent populations, and vaccinations. The article references multiple studies that have yielded variable results. In some cases cited in the report, caged systems had a decreased Salmonella risk, in some there were no differences, and in some caged systems had a higher Salmonella risk.

Dewulf states that multiple factors are to be considered and that use of cages in the production environment may not be the sole, or even primary, risk factor for increased Salmonella prevalence. Specifically the author states:

> This does not necessarily mean that there is a causal relationship between the housing type and infection. On the contrary, it is more likely that the effect attributed to the housing system is in reality influenced by several other production characteristics, such as magnitude of the flock or herd, age of the building, probability of previous Salmonella infections on the farm, etc.

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[19] Davies, R., and C. Wray, 1996. Persistence of Salmonella enteritidis in poultry units and poultry food. *Br Poultry Science*. 37(3):589-596.
[20] Davies, R. H. and M. Breslin, 2003. Persistence of Salmonella Enteritidis phage type 4 in the environment and arthropod vectors on an empty free-range chicken farm. *Environ. Microbiol*. 5:79-84.
[21] Wales, A., M. Breslin, B. Carter, R. Sayers, and R. Davies, 2007. A longitudinal study of environmental Salmonella contamination in caged and free-range layer flocks. *Avian Pathology*. 36(3):187-197.

The Huneau-Salaün et al. (2009) study sought to identify risk factors for Salmonella contamination in French laying hens at the end of their laying cycle. The study involved conducting a survey to identify potential risk factors and sampling certain farms to establish the prevalence of Salmonella. This study has a number of limitations. Different sampling schemes were used for each production system. Similar to the EFSA study, caged environments were assessed by pooled (hand collected) fecal samples while cage-free environments were sampled with boot swabs. The author acknowledges that the differences observed could be related to the higher sensitivity of fecal sampling: "The odds of a Salmonella infection were significantly higher in caged flocks than in on-floor flocks. This might be related to the higher sensitivity of pooled feces samples taken in cage poultry-houses than that of boot swabs taken from on-floor flocks." The study also contains some contradictory data. Results indicate that on-floor (i.e., cage-free) systems had a substantially *higher* prevalence of SE with 43% of cage-free systems being positive for SE as compared to 14.3% caged systems being positive for SE. Also, the caged operations sampled were larger than cage-free operations. As explained regarding the EFSA 2007 study, flock size has been implicated as a risk factor for Salmonella contamination; it is therefore impossible to determine whether differences observed were a result of the type of production system or the size of the flock tested.

In the Holt et al. (2010) paper, the authors conducted a detailed review of the literature on the effect of housing type on egg safety. The authors conclude that research on this topic is limited, what exists was mostly conducted in Europe, and that more studies are necessary. Specifically, Holt et al. (2010) state: "Much of the most recent information on this topic result[s] from studies conducted in the EU and this information must then be applied to conditions found in the US industry. Although many similarities do exist, the EU and US egg industries differ sufficiently to make such extrapolations difficult and new studies geared more to egg production in the United States are warranted." Holt et al. also state that "[t]here is no general consensus demonstrating the superiority of one housing situation over another regarding food safety and egg quality." Specific reference is made to studies by others that have found varying results; in some studies caged production systems resulted in a higher incidence of Salmonella positive environments while the opposite was true in other studies.

Your petition argues on p. 63 that "a study conducted by the American Journal of Epidemiology, concluded that people who ate eggs from caged hens had almost double the probability of contracting Salmonella food poisoning compared to those who did not eat eggs from hens confined in cages." This study was not designed to evaluate the risk associated with different types of production systems but rather to confirm that consumption of raw eggs is a risk factor for SE illness. We note that within the study both battery cage and free range production systems were associated with risk. Specifically, Mølback and Neimann state: "In the present study, 257 case patients and 412 controls had used eggs in household meals, and among these individuals we found that illness was associated with eggs from battery, deep litter, and free-range production, whereas we were unable to demonstrate an association with organic eggs or eggs sold at barnyards"[22].

[22] Mølbak and Neiman, Risk Factors for Sporadic Infection with Salmonella Enteridis, (2002). *American Journal of Epidemiology.* 156(7):654-661. (Pet. Footnote 237).

2. The Information Submitted Does not Support the Proposed Labeling Requirements

You also reference a "massive August 2010 egg recall caused by an SE outbreak from caged production facilities" (Pet. at 57). You assert that because of a "connection between SE risk and cage production" and the August 2010 egg recall, mandatory disclosure of production method is necessary for consumers "to mitigate their health risk" (Pet. at 57-58). As explained above, you have not established a causal link between Salmonella risk and the method of egg production. In addition, the August 2010 egg recall, extensively referenced in your petition as a reason to require labeling of egg production method (Pet. at 58-62), is not informative regarding the relative risk of egg production systems. Given the high percentage of eggs produced by caged hens relative to other production methods,[23] it would be expected that a particular recall would be associated with cage-produced eggs.

In addition, the 2010 outbreak you cite stemmed from conditions that occurred before egg producers were subject to FDA's shell egg regulation. Egg producers are now required to implement extensive measures to prevent SE from contaminating eggs (21 CFR Part 118). *See also supra* section I.B.1. FDA mandates that egg producers have and implement SE Prevention Plans with measures to address pullets, biosecurity, pest control, refrigeration, and cleaning and disinfection (21 CFR 118.4). Egg producers are subject to comprehensive testing requirements, including mandatory environmental testing of every poultry house for SE, and testing of eggs if the environment tests positive (21 CFR 118.5, 118.6). Further, if an egg tests positive for SE, all eggs from that house must be treated to destroy any SE that may be present unless subsequent test results support a return to the table egg market (21 CFR 118.6).

Your petition does not show that mandating that eggs be labeled with the method of production would provide consumers with meaningful information regarding the relative risk of Salmonella. Further, because there is no demonstrated link between Salmonella prevalence and the method of production, the production method for eggs cannot be a material fact on this basis.

C. PRODUCTION METHOD AND CONSUMER INTEREST

1. Evaluation of Information Submitted

To support your argument that the current labeling of shell eggs fails to reveal to consumers certain information that substantially influences their purchasing decisions, you submit exhibits containing the results of several consumer surveys (Pet. at 2). You assert that U.S. consumers "are willing to pay substantially more for eggs represented to them as produced under standards that ensure some degree of animal welfare" (Pet. at 3). Based on our review of the exhibits submitted with the petition, we conclude that some of your exhibits (Zogby, 2000[24]; Animal

[23] According to your petition, over 95% of eggs come from caged hens (Pet. at 3).
[24] Report from Gene Bauston, Farm Sanctuary to Rebecca Wittman, Zogby International on a telephone survey of 1,204 U.S. adults conducted by Zogby International September 15-18, 2000 (Pet. Ex. 5).

Welfare Institute, undated[25]; Zogby, 2007[26]; Lusk, Norwood, and Prickett, 2007[27]) indicate that there are some U.S. consumers with concerns about animal welfare who may desire products labeled as protective of animal welfare. While the agency's position is that consumer interest alone is not a material fact; nevertheless, even if it was, these studies do not provide sufficient information to conclude that there is a widespread or strong desire or demand among the U.S. population for the type of mandatory labeling requirements proposed in the petition. Three limitations of the exhibits are explained below.

Inappropriate wording of questions: Some of the wording used in the surveys, e.g., "crowding," "cannot stretch their wings," "starving" (Zogby, 2000), "forced" (Zogby, 2007) is "loaded" or inflammatory within the context of the question and prone to cause more extreme responses that bias toward the emotions created by the wording. Loaded words or questions present respondents with only one dimension of an issue and can cause respondents to answer according to presented dimensions (Litwak, 1956[28]).

In addition, the wording of the questions tends to create social desirability bias, where responses do not necessarily represent respondents' true opinions because respondents want to create a favorable impression, such as appearing to be more compassionate (Holbrook, Green and Krosnick, 2003[29]). Research has shown that telephone surveys, such as the ones submitted as exhibits to the petition (Zogby, 2000; Zogby, 2007; Lusk, Norwood, and Prickett, 2007), are among the types of surveys that are more vulnerable to social desirability bias (Holbrook, Green, and Krosnick, 2003).

Lack of methodological details and limited applicability of findings: Some studies (World Society for the Protection of Animals, 2009; The Humane Touch, 2007[30]) did not provide any information on important details of the survey methodology, e.g., sample universe and selection method for respondents. Without such information, it is impossible to assess the degree to which the findings can be applied at a national level. In addition, some surveys (Lusk, Norwood, and Prickett, 2007;[Rauch and Sharp, 2004; Conner, et al., 2005; University of California, Santa Cruz, 2005; Rauch and Sharp, 2005][31]) were conducted on only certain U.S. population segments such as Ohio residents (Rauch and Sharp, 2005), Michigan residents (Conner, et al.,

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[25] A collection of findings from 23 surveys about consumer perceptions of farm animal welfare, by the Animal Welfare Institute. (Pet. Ex. 13).
[26] Report from Gene Bauston, Farm Sanctuary to Rebecca Wittman, Zogby International on a telephone survey of 1,013 likely voters in the U.S. conducted by Zogby International January 5-9, 2007 (Pet. Ex. 18).
[27] Lusk, JL, Norwood, FB, Prickett, RW. 2007. Consumer preferences for farm animal welfare: results of a nationwide telephone survey. Department of Agricultural Economics, Oklahoma State University, Working Paper (Pet. Ex. 73).
[28] Litwak, E. (1956). A Classification of Biased Questions. *American Journal of Sociology*, 182-186.
[29] Holbrook, A. L., Green, M. C., & Krosnick, J. A. (2003). Telephone versus face-to-face interviewing of national probability samples with long questionnaires: Comparisons of respondent satisficing and social desirability response bias. *Public Opinion Quarterly*, 67(1), 79-125.
[30] World Society for the Protection of Animals, 2009; The Humane Touch, 2007 from A collection of findings from 23 surveys about consumer perceptions of farm animal welfare, by the Animal Welfare Institute (Pet. Ex. 13).
[31] Rauch and Sharp, 2004; Conner, et al., 2005; University of California, Santa Cruz, 2005; Rauch and Sharp, 2005 from A collection of findings from 23 surveys about consumer perceptions of farm animal welfare, by the Animal Welfare Institute (Pet. Ex. 13).

2005), "central California shoppers" (University of California, Santa Cruz, 2005) or were conducted in other countries such as United Kingdom (Harper, 2002[32]) and Australia (Rolfe, 1999[33]). Thus, the results do not statistically reflect U.S. national opinions.

Doubts about the suitability of using contingent valuation results as a preference indicator for policy decisions: Several studies referenced in the petition (Bennett and Larson, 1996[34]; Bennett and Blaney, 2003[35]) rely on contingent valuation surveys. Contingent valuation is a survey-based method often used to place a monetary value on environmental goods and services not usually bought and sold in the marketplace, such as air pollution (Carson, 2000[36]). The extent that contingent valuation estimates can be used as a measure of individuals' preference toward an issue is debatable, particularly when a single issue is not presented in the context of other issues, such as poverty, health care, food safety, and the environment. A review of recent contingent valuation research suggests that many results are biased and inconsistent (Hausman, 2012[37]). In addition, social desirability is another factor that can limit the usefulness of contingent valuation estimates as a measure of people's demand for a certain policy or course of action. Under social desirability, people's responses to survey questions do not necessarily represent their true opinions because they want to create a favorable impression of themselves during the survey (Holbrook, Green and Krosnick, 2003).

2. *The Information Submitted Does Not Support the Proposed Labeling Requirements*

You argue that factors such as consumers' "demand for higher animal welfare standards" and willingness "to pay more for eggs from hens raised in what they perceive to be a 'humane' manner" support the need for regulation (Pet. at 8, 9). As described above, there are significant limitations concerning the information you submitted, rendering it insufficient to conclude there is widespread or strong desire or demand for the type of labeling requirements you propose. In addition, consumer preference alone does not constitute a material fact and is not a permissible basis for FDA to require labeling. See International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73 (2d Cir. 1996) (finding that consumer interest alone is not a sufficient government interest on which to compel labeling). Similar arguments regarding consumer interest were made and rejected in Stauber and ABI. As the court stated in Stauber, "in the absence of evidence of a material difference . . ., the use of consumer demand as the rationale for labeling would violate [the Act]." 895 F. Supp. at 1193. Similarly, in ABI the court noted plaintiffs' "fail[ure] to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has

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[32] Harper, GC. (2002). Consumer perception of organic food production and farm animal. *British Food Journal*, 104,3: 287-299 (Pet. Ex. 55).
[33] Rolfe, J. (1999). Ethical Rules and the Demand for Free Range Eggs, *Economic Analysis and Policy* 29,2, 187-206 (Pet. Ex. 115).
[34] Bennett, R. & Larson, D. (1996). Contingent Valuation of the Perceived Benefits of Farm Animal Welfare Legislation: An Exploratory Survey, 47(2) *Journal of Agricultural Economics* 224 (Pet. Ex. 113).
[35] Bennett, R.M. & Blaney, R.J.P. (2003). Estimating the Benefits of Farm Animal Welfare Legislation Using the Contingent Valuation Method, *Journal of Agricultural Economics* 29, 85-98 (Pet. Ex. 116).
[36] Carson, R. T. (2000). Contingent valuation: a user's guide. *Environmental Science & Technology*, 34(8), 1413-1418.
[37] Hausman, J. (2012). Contingent valuation: From Dubious to Hopeless. *The Journal of Economic Perspectives*, 26(4), 43-56.

been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact." 116 F. Supp. 2d at 179.

D. COMMENTS

FDA received and reviewed more than 6000 comments to the petition. All but approximately a dozen expressed support for or were neutral on the petition. Of the comments supporting the petition, the majority were nearly identical form letters which presented the opinions of the writers, but did not provide any data (i.e., studies or research papers) or other information to support the opinions. Similarly, the comments opposing the petition did not provide FDA with any data that affected the agency's position.

E. OTHER ARGUMENTS

1. Materiality of Production Method

You assert that "[p]roduction method claims such as hen caging conditions" are "especially material" because they are "difficult to verify by sensory perception at the time of purchase or afterward" (Pet. at 17). You identify cage-free eggs as an example of a "credence good" because consumers cannot evaluate by looking at or eating an egg whether it was produced by a free-range hen or by a hen confined in a cage. Although such information may not be readily apparent to a consumer, this does not make it material. Similar logic would apply to other circumstances where consumer interest was not a material fact. In Stauber, 895 F. Supp. at 1178, consumers could not tell by looking at or consuming milk whether it was produced from cows treated with rbST, but this information was not a material fact. Similarly, in ABI, 116 F. Supp. 2d at 166, consumers could not tell by looking at or consuming a food that it was rDNA-produced, but this was not a material fact.

2. Other Labeling Requirements

In your petition you stated that FDA has promulgated food labeling requirements in contexts similar to the one discussed in the petition (Pet. at 55). To support this point, you cited statements for dietary supplements (21 CFR 101.93) i.e., "Structure/Function" claims and a regulation concerning the term "Fresh" (21 CFR 101.95). In contrast to the mandatory egg production labeling you propose, the regulations you cite involve voluntary statements. Manufacturers are not required to label foods with any type of nutrient content claim, health claim or structure/function claim. Likewise, manufacturers are not required to label products as "fresh." Also, each of the claims you reference is specifically related to a fact about the food itself, rather than the means of production. As the ABI court noted, "[d]isclosure of the conditions or methods of manufacture has long been deemed unnecessary under the law." (*citing* U.S. v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar, 265 U.S. 438, 445 (1924) ("When considered independently of the product, the method of manufacture is not material. The [A]ct requires no disclosure concerning it.").

F. FDA'S ENFORCEMENT AUTHORITY

As a matter of law, FDA cannot require the labeling of shell eggs to include production methods under 21 U.S.C. § 321(n). The production method is not a material fact. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 n.10 (D.D.C. 2000). As explained above, FDA has considered the petition and its supporting exhibits and determined that the information submitted is insufficient to establish that, in all cases, based on production method alone, a difference exists in either the nutritional properties or the associated Salmonella risk between eggs from caged hens and free-range hens that would warrant the proposed mandatory labeling requirements. In addition, consumer interest alone is not sufficient to support your request.

Moreover, additional labeling requirements are not necessary for FDA enforcement. If information on an egg label is false or misleading, as you assert some current labels are (Pet. at 11-16), FDA may bring an enforcement action under the misbranding provisions of the Act (21 U.S.C. 343(a), 343(r), 331-334). You acknowledge this existing authority (Pet. at 34, 44-50, 53-54).

FDA determines whether to take enforcement action against misbranded food on a case-by-case basis. For example, the agency recently issued a Warning Letter stating that products were misbranded within the meaning of section 403(a)(1) of the Act because the term "natural" was used to describe a food that contains a synthetic ingredient. See Food and Drug Administration, Nov. 16, 2011 Warning Letter to Alexia Foods, available at http://www.fda.gov/ICECI/EnforcementActions/ WarningLetters/ucm281118.htm (last visited Aug 7, 2013). FDA has also taken regulatory action against food manufacturers that make unsubstantiated health claims about their food products. For example, on March 24, 2011, FDA sent a Warning Letter for labeling claims stating that sprout products "may have desirable effects, for example reduce the risk of breast cancer." See Food and Drug Administration, Mar. 24, 2011 Warning Letter to Jonathan's Sprouts, Inc., available at http://www.fda.gov/ForConsumers/Consumer Updates/ucm248745.htm (last visited Aug 7, 2013). Use of these unsubstantiated health claims rendered the sprout product misbranded under section 403(r)(1)(B) of the Act.

In addition to Warning Letters, FDA recently sought and obtained a permanent injunction against a juice manufacturer that distributed juice products that were misbranded under section 403(a). United States v. Jonlly Fruits, Inc. et al., No. 13-cv-1043 (Doc. No. 4) (D.P.R. Jan. 17, 2013). The manufacturer's juice was misbranded because it was labeled as "natural," although it contained artificial ingredients, and because it contained inaccurate nutrient content claims on its labels such as "light," "100% vitamin C," "Rich in Calcium," and "No Sugar." United States v. Jonlly Fruits, Inc. et al., No. 13-cv-1043 (Doc. No. 1) (D.P.R. Jan. 15, 2013). FDA has sought and obtained injunctions against other firms that have distributed in interstate commerce misbranded food bearing inaccurate nutrient content claims. See, e.g., United States v. Butterfly Bakery, Inc. et al., No. 13-cv-669 (Doc. No. 7) (D.N.J. Mar. 5, 2013) (baked goods misbranded because their labels inaccurately represented the amount of fat and sugar in the products); United States v. Natural Ovens Bakery, Inc., No. 06-cv-147 (Doc. No. 3) (E.D. Wis. Feb. 3, 2006) (baked goods misbranded because they failed to declare the correct amount of various nutrients, including vitamin C, Zinc, Calcium, and Omega-3 fatty acids).

G. COMPETING AGENCY PRIORITIES

Finally, FDA appreciates your concern that egg labels not be false or misleading and your desire for greater FDA action in this regard. However, even setting aside the legal and scientific concerns discussed above, we deny your petition for the additional and independent reason that the rulemaking you request is not the best use of the agency's limited resources.

United States consumers spend twenty-five cents of every consumer dollar on products regulated by FDA, and, of this amount, approximately 75 percent is spent on foods. FDA regulates $417 billion worth of domestic food and $49 billion worth of imported foods. FDA's responsibility in the food area covers nearly all domestic and imported food, including, in addition to shell eggs, fruits and vegetables, seafood, grain products and pastas, cereal flours and related products, acidified and low acid foods, infant formula, dietary supplements, dairy products, food and color additives, bottled drinking water, juice, and other beverages. In addition, FDA regulates food ingredients, packaging, and labeling. There are hundreds of thousands of domestic and foreign registered food facilities and farms subject to FDA regulation.. In addition to developing regulations, FDA's oversight of the food supply involves a wide range of activities, including inspecting food facilities, overseeing the safety of imported foods, responding to foodborne illness, developing guidance documents, and, where appropriate, seeking enforcement action.

FDA is currently engaged in an unprecedented number of novel and complex rulemakings to implement the FDA Food Safety Modernization Act of 2011 ("FSMA"). As part of FSMA implementation, FDA is developing regulations to, among other things:

- establish science-based minimum standards for hazard analysis and risk-based preventive controls (21 U.S.C. § 350g(n)(1));
- clarify the activities that are included as part of the definition of the term "facility" (21 U.S.C. § 350d note);
- establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables (21 U.S.C. § 350h);
- specify the content and requirements of foreign supplier verifications programs (21 U.S.C. § 384a(c));
- protect against intentional adulteration of food (21 U.S.C. § 350i(b));
- establish sanitary transportation practices for all persons engaged in transporting food (21 U.S.C. § 350e(b) and note); and
- establish a new program involving the accreditation of third party auditors/certification bodies (21 U.S.C. § 384d(c)(5)(C)).

In addition to FSMA rulemakings, FDA currently is engaged in numerous other rulemakings including:

- Food Labeling; Revision of the Nutrition and Supplement Facts Labels (21 U.S.C. § 343);
- Food Labeling; Calorie Labeling of Articles of Food Sold in Vending Machines (21 U.S.C. § 343) (required by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act);
- Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments (21 U.S.C. § 343)(required by the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act));
- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumer in One Eating Occasion; Dual Column Labeling; and Modifying the Reference Amounts Customarily Consumed (21 U.S.C. § 343);
- Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements, and Records and Reports (21 U.S.C. § 350a);
- Use of Materials Derived From Cattle in Human Food and Cosmetics (21 U.S.C. 342(a)(2)(C), (a)(3), (a)(4), (a)(5), 361(c), and 371(a)).

Given the scope of FDA's responsibilities regarding the food supply, the agency must make difficult choices regarding how to use its limited resources. For every rulemaking the agency undertakes, there are many others it cannot. These other rulemakings are of lower priority and are not undertaken for reasons that may include that they are not statutorily-mandated or that they address less urgent public health and food safety problems. In light of the agency's many competing priorities, and based on our careful consideration of the information you submitted, we have determined that the rulemaking you requested is not a good use of agency resources.

III. Conclusion

For each of the reasons discussed above, we conclude that your petition does not provide sufficient grounds for the agency to revise the current labeling requirements for shell eggs to provide for certain terms related to egg production methods and to require such labeling. Therefore, FDA is denying your petition in accordance with 21 CFR 10.30(e)(3).

If you have any questions regarding the labeling of eggs, please contact the Office of Nutrition, Labeling, and Dietary Supplements at telephone number 240-402-2371.

Sincerely,

Michael M. Landa
Director
Center for Food Safety
and Applied Nutrition

APPENDIX

List of References

1. *See, e.g.*, Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access) (providing guidance to egg producers on certain provisions in the egg rule concerning the management of production systems that provide laying hens with access to the outdoors), *available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Eggs/ucm360028.

2. *See* Guidance for Industry: A Food Labeling Guide (8. Claims) Question and Answers N21 and N22.

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9. Stadelman, W.J. and O.J. Cotterill, 1995. *Egg Science and Technology, 4th Ed.* Food Products Press. The Haworth Press, Inc, New York-London. Pp. 177-194.

10. Bell, D.D., and W.D. Weaver Jr., 2002. *Commercial Chicken Meat and Egg Production, 5th Ed.* Springer. Pp. 1116 and 1124.

11. We note that you acknowledge that "not all eggs that qualify as 'free range' are the pastured eggs that were the subject of these studies…." (Pet. at 28).

12. 21 CFR 101.9(c)(2)(i), (c)(3), and (c)(8)(ii).

13. 21 CFR 101.9(c)(8)(ii)(B); 21 CFR 101.13(i)(3).

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17. Huneau-Salaün, et al., 2009. Risk factors for Salmonella enterica subsp. Enterica contamination in 519 French laying hen flocks at the end of the laying period. *Prev Vet Med* (89): 51-58 (Pet. Ex. 94).

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22. Mølbak and Neiman, Risk Factors for Sporadic Infection with Salmonella Enteridis, (2002). American Journal of Epidemiology. 156(7):654-661. (Pet. Footnote 237).

23. According to your petition, over 95% of eggs come from caged hens (Pet. at 3).

24. Report from Gene Bauston, Farm Sanctuary to Rebecca Wittman, Zogby International on a telephone survey of 1,204 U.S. adults conducted by Zogby International September 15-18, 2000 (Pet. Ex. 5).

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34. Bennett, R. & Larson, D. (1996). Contingent Valuation of the Perceived Benefits of Farm Animal Welfare Legislation: An Exploratory Survey, 47(2) *Journal of Agricultural Economics* 224 (Pet. Ex. 113).

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36. Carson, R. T. (2000). Contingent valuation: a user's guide. *Environmental Science & Technology*, 34(8), 1413-1418.

37. Hausman, J. (2012). Contingent valuation: From Dubious to Hopeless. *The Journal of Economic Perspectives*, 26(4), 43-56.